REMARKS/ARGUMENTS

Claims 1-5 and 7-20 remain in this application.

Rejection Under 35 USC 112

I

Claim 13 was rejected under 35 USC 112, first paragraph. The Office Action asserts that "claim 13 lacks written description because while the claim and specification state no more than a certain percent of water is left after drying at 105° C, the time if which the dosage form is dried was not recited." See Page 3 of the Office Action. Applicants respectfully disagree, as the time for the weight of the dosage form to stabilize once heated to 105°C will obviously depend upon the formulation of the dosage form (e.g., the water content of the dosage form at room temperature). Accordingly, Applicants respectfully request that this rejection be withdrawn.

II

Claim 12 was rejected under 35 USC 112, second paragraph. See page 4 of the Office Action. The Office Action asserts "claim [12] recites that he dosage form meets USP dissolution requirements for immediate release, but the claim does not describe how the requirement would be met." See page 4 of the Office Action. Applicants respectfully disagree. As set forth on page 3, lines 6-11 of the specification, the USP sets forth a specific requirement for each active. As set forth on page 3, lines 6-11 of the specification;

> For example, for acetaminophen tablets, USP 24 specifies that in pH 5.8 phosphate buffer, using USP apparatus 2 (paddles) at 50 rpm, at least 80% of the acetaminophen contained in the dosage form is released therefrom within 30 minutes after dosing, and for ibuprofen tablets, USP 24 specifies that in pH 7.2 phosphate buffer, using USP apparatus 2 (paddles) at 50 rpm, at least 80% of the ibuprofen contained in the dosage form is released therefrom within 60 minutes after dosing. See USP 24, 2000 Version, 19 – 20 and 856 (1999).

Thus, Applicants believe that the claim 12 is clear, as the specific requirements are set forth in the USP. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Obviousness Double Patenting Rejections

Claims 1-5 and 7-20 were provisionally rejected on the ground of nanstatutory obviousness-type double patenting. See pages 5-6 of the present application. At the current time, Applicants believe that the obviousness-type double patenting rejections are moot as the subject matter of the present application has yet to issue into a patent.

Rejections Under 35 USC 103

Claims 1-5 and 7-20 were rejected under 35 USC 103(a) as being unpatentable over Reuter et al (US Patent No. 4,835,187) in view of Dressman et al. (US Patent No. 5,789,393) and in further view of Siebert et al. (US Patent No. WO 00/09090). See Pages 7-12 of the Office Action. According to the Office Action,

> "Reuter et al. teach an immediate release composition in chewable solid dosage form. . . . Reuter et al do not teach the composition comprising the matrix comprising the hydroxypropylmethylcellolose. Dressman et al. teach that a 2% aqueous solution of a high molecular weight HPMC advantageous in the practice of the invention has a viscosity of about 30,000 mPa.S . . . Also, Reuter et al do not explicitly teach the instantly claimed particle diameters ranging from about 150 μm to about 400 μm and the water-disintegratable compressible carbohydrate being from about 50 to about 80 percent. Seibert et al. teach the use of microcapsules having a particle size ranging from between about 50 to about 3,000 microns . . . Additionally, Seibert et al. teach the use if 5-60% of sugar alcohol . . .Siebert et al. list examples of sugar and sugar alcohols such as mannitol, sorbtitol, and xylitol. . . . . It would have been obvious to a person having ordinary skill in the art at the time of the invention to combine the teachings of Reuter et al., Dressman et al., and Seibert et al. to devise a tablet capable of being chewed or disintegrated in the oral cavity prior to swallowing."

See Pages 9-11 of the Office Action. Applicants respectfully disagree.

As noted above in the Office Action, "Reuter et al do not teach the composition comprising the matrix comprising the hydroxypropylmethylcellolose." Dressman et al. discloses the use of cellulose ethers, but as an active agent, not part of a matrix of a dosage form. Accordingly, Dressman et al., does not disclose, or suggest, the use of cellulose ethers in combination with "a plurality of particles comprising a pharmaceutically active ingredient" as recited in independent claims 1 and 14.

Similarly, Siebert et al. also fails to disclose, or suggest, the use of cellulose ethers in combination with "a plurality of particles comprising a pharmaceutically active ingredient" as recited in independent claims 1 and 14.

Further, as noted on page 11, lines 3-6 of the application, Applicants "unexpectedly found that the addition of high weight average molecular weight hydroxyalkylcellulose to the matrix results in a dosage form that delivers a good mouthfeel through a rapid viscosity build without an initial intense drying sensation of the mouth and without a subsequent excessive slimy or gummy feel during mastication."

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP-5016/WEM.

Respectfully submitted,

By:____/William E. McGowan/_____
William E. McGowan
Reg. No. 39,301

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2197